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Mie Takahashi

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WENDEROTH, LIND & PONACK, L.L.P.

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EXAMINER

COUNTS, GARY W

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/937,730	Applicant(s) TAKAHASHI ET AL.	
	Examiner GARY W. COUNTS	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,12,27,31,41,45,49,53 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,12,27,31,41,45,49,53, 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

The amendment filed March 10, 2008 is acknowledged and has been entered. Claims 5, 12, 27, 31, 41, 45, 49, 53 and 60 are pending and are under examination.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1641

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 5, 12, 27, 31, 41, 45, 53 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu (US 6,284,194) in view of Nanbu et al (US 6,130,055) or Uenoyama et al (US 5,856,117).

Chu discloses an analytical device and method of making the device. Chu teaches that the device comprises a porous reaction membrane and at least one receptor immobilized in a limited region (col 1, lines 40-50) (reaction layer and reactive components). Chu teaches applying a surfactant (surface active agent) to the reaction membrane and allowing to dry (col 1, lines 55-67). Chu teaches that drying can be performed by air drying at room temperature or by warm air with good ventilation (col 9, lines 30-43). Chu teaches the surfactant can be a surfactant such as polyoxyethylene (23), polyoxyethylene sorbitan monolaurate or polyoxyethylene sorbitan monooleate (col 8). Chu teaches that all (entire) or most (part) of the surface (col 5, lines 27-32, col 9) is exposed to the surfactant.

Chu differs from the instant invention in failing to teach the surface active agent comprises a surface active agent having sugar in a hydrophilic part.

Nanbu et al disclose surfactants (surface active agent) used in bioassays. Nanbu et al disclose that the surfactant (surface active agent) can be polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monooleate, or sucrose monolaurate (contains sugar in hydrophilic part) (col 3, lines 26-35). Nanbu et al teaches that the use of a surfactant improves the assay sensitivity.

Uenoyama et al disclose surfactants (surface active agents) used in bioassays. Uenoyama et al disclose that the surfactant (surface active agent) can be polyoxyethylene (23), polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monooleate, n-octyl-B-D-thioglucoside (sugar in hydrophilic part) or sucrose monolaurate (contains sugar in hydrophilic part) (col 3, line 59 – col 4, line 13). Uenoyama et al disclose that this surfactant improves the assay sensitivity.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute sucrose monolaurate surfactants (surface active agent) as taught by Nanbu et al for the surface active agent of Chu because Nanbu et al teaches that the use of a surfactant improves assay sensitivity. Further Chu teaches that polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate are surfactants which can be used in the analytical device and the method of making the device and Nanbu teaches the equivalence of polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate surfactants to sucrose monolaurate surfactants for their addition in bioassays and the selection to any known equivalents to replace the surfactants of Chu would be within the level of ordinary skill in the art and one of ordinary skill in the art would have a reasonable expectation of success using the surfactants (surface active agents) of Nanbu et al in the method and device of Chu.

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to substitute the n-octyl-B-D-thioglucoside (sugar in hydrophilic part) or sucrose monolaurate surfactants (surface active agent) as taught by Uenoyama

Art Unit: 1641

et al for the surface active agent of Chu because Uenoyama et al teaches that the use of a surfactant improves assay sensitivity. Further Chu teaches that polyoxyethylene (23), polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate are surfactants which can be used in the analytical device and the method of making the device and Uenoyama et al teaches the equivalence of polyoxyethylene (23), polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate surfactants to sucrose monolaurate and n-octyl-B-d-thioglucoside surfactants for their addition in bioassays and the selection to any known equivalents to replace the surfactants of Chu would be within the level of ordinary skill in the art and one of ordinary skill in the art would have a reasonable expectation of success using the surfactants (surface active agents) of Uenoyama et al in the method and device of Chu.

With respect to claims 41 and 45 as recited in the instant claims. Chu teaches that drying can be performed by warm air in good ventilation. Therefore, Chu teaches drying moving air (wind) and thus Chu teaches wind drying as recited in the instant claims.

5. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chu in view of Nanbu et al or Uenoyama et al as applied to claims 5, 12, 27, 31, 41, 45, 53 and 60 and further in view of Iwata et al (US 5,912,139).

See above for teachings of Chu, Nanbu et al and Uenoyama et al.

Chu, Nanbu et al and Uenoyama et al differ from the instant invention in failing to teach the reactive layer is dried by freeze drying.

Iwata et al disclose producing a test strip by impregnating a carrier with a solution comprising components. Iwata et al disclose that the impregnated carrier is then dried by freeze drying (col 6, lines 48-59). Iwata et al disclose that the components can be surfactants (col 6, lines 3-14 and col 10, lines 10-22). Iwata et al disclose that freeze drying thoroughly removes water from the carrier (col 6, line 53). Iwata et al disclose that this provides for a test strip, which provides high sensitivity and high accuracy measurement and excellent storage stability (abstract & col 2, lines 22-43).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate freeze drying as taught by Iwata et al into the modified method of Chu because Iwata et al teaches that freeze drying thoroughly removes water from the carrier and Iwata et al also teaches that this provides for a test strip which provides high sensitivity and high accuracy measurement and excellent storage stability.

Response to Arguments

6. Applicant's arguments filed March 10, 2008 have been fully considered but they are not persuasive.

Applicant argues that polyoxyethylene sorbitan monolaurate is a slightly yellow liquid surface active agent at normal temperature and normal pressure and also that polyoxyethylene sorbitan monooleate is a slightly yellow liquid surface active agent at normal temperature and normal pressure. Applicant states that from a physical standpoint, drying the liquid surface active agent at normal temperature and normal pressure means: 1) evaporating the surface Active agent itself, or 2) evaporating the

Art Unit: 1641

surrounding water without drying the surface active agent. Applicant states that drying the surface active agent itself, does not make sense because the surface active agent does not remain on a test specimen. Following option 2), evaporating surrounding water without drying the surface active agent remains on the test specimen in liquid form because the surface active agent is in liquid state at normal temperature and normal pressure. Applicant states that with the surface active agent which leaves a liquid material on a test specimen after having a drying process, the test specimen using such surface active agent would cause a decline of long-term preservation stability. Applicant states that even though a high sensitivity state could eventually be obtained at an early phase after manufacturing, the sensitivity will decline during the period until the user actually uses the product, after marketing. Accordingly, the user would obtain incorrectly measured results based on a test specimen with decreased sensitivity.

These arguments are not found persuasive for the following reasons. With respect to the yellow color of polyoxyethylene sorbitan monooleate and polyoxyethylene sorbitan monolaurate as indicated by applicant it is unclear what applicant is trying to indicate. Does the color not provide for drying or solidification? Does the color affect the device? Further, it is noted that applicant did not mention sucrose monolaurate or n-octyl-B-D- thioglucoside. The combination of the instant references teach the same surface active agents as the applicant and therefore it does not appear that the color of the surface active agents is relevant. Applicants arguments directed to the drying process are not found persuasive because applicant has not provided evidence that the

Art Unit: 1641

surface active agents of the combined references are not or would not be solidified when dried and further because Chu is teaching the same drying process as claimed by applicant in the currently recited claims (e.g. claim 41 air drying (normal temp. normal pressure). Since the combination of references teach the same surface active agents and the same drying process as claimed by the applicant the drying process would ensure long-term preservation stability and increasing preservation circumstance freedom.

Applicant argues that there are no teachings nor suggestions regarding preservation stability in the teachings of Chu, Nanbu et al., and Uenoyama et al. This is not found persuasive because the fact that Applicant recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious (see *Ex parte Obiaya*, 227 USPQ 58, 60 (Db. Pat. App. & Inter. 1985).

Applicant argues that the use of a surfactant which has sugar in a hydrophilic part which is able to become solid when dried, results in many advantageous properties, which would not have been predicted based on the teachings of the prior art. This is not found persuasive because of reasons of record which have stated that the surfactants provide improved sensitivity in assays (it is noted that this is one of the same advantages disclosed in the current application on page 10) and thus the substitution would have been predictable. Further, as stated in the previous office action the selection to any known equivalent to replace the surfactants of Chu would be within the level of ordinary skill in the art and as also stated in the previous office action the

Art Unit: 1641

selection of reagents can be affected by many factors such as the specific requirements of an assay the availability of reagents as well as economic factors (i.e. costs of the reagents) and finally as indicated above the fact that Applicant recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious (see *Ex parte Obiaya*, 227 USPQ 58, 60 (Db. Pat. App. & Inter. 1985).

Examiner acknowledges submission of patent documents including Kuo et al., Doe, Shields et al., Kawasaki et al, Tanaka et al., Koyama et al., Kadota et al., Matsuura et al. to reinforce importance of preservation environment and long term preservation stability. However, the extent of their relevancy is not on point because it is maintained that the obvious combined teachings of the cited references on record, is consonant to the claimed invention.

Conclusion

7. No claims are allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1641

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/
Examiner, Art Unit 1641

/GAILENE R. GABEL/

Primary Examiner, Art Unit 1641